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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,741	12/05/2003	Jan Lewandowski	34968US3	1343
116	7590	06/15/2004	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			JAWORSKI, FRANCIS J	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

10/729,741

Applicant(s)

LEWANDOWSKI, JAN

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

[Parenthesized claim numbers found in this action pertain to the specific claim or claims towards which the immediately preceding rejection statement is directed.]

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-15, 23-24,35, 38-39, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler et al (US6093150).

Chandler et al is directed to an ear diagnosis probe apparatus and method of ear disorder diagnosis including structure and steps for an array 6 for transceiving signals for ear disorder detection and supporting means 2, 4 for the array, and steering means for controlling the transducers to fire along sequentially changing scan angles in differing directions to form the scanned image, see col. 11 lines 10-45.in order to determine the existence of an ear disorder from the imaged information. (Claims 14, 23-24,35, 43).

A curved array and support with each transducer emitting into a different direction and its use are contemplated, see col. 7 top. (Claims 15, 38-39)..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al (US6093150) in view of either Lang et al (US5941825) or Vilkomerson (US5669388).

Chandler et al teaches an ear disorder detecting apparatus and diagnostic method including means 6 for and associated step of transmitting and receiving a plurality of ultrasound signals, a means for and step of directing ... in different directions is taught by virtue of suggested array face curvature col. 7 top and/or the subsequent suggestion is made to image by movement or synthetic aperture formation to provide locational specificity for the 2D or 3D image. Chandler et al suggests processing circuitry which receives the echo signals for detecting ear disorders such as detecting otitis media or middle ear infection via interface detection, col. 2 lines 46-61, as well as B-mode (conventional anatomic range and azimuth scanning), Doppler and quantitative assessments, see col. 6 lines 44-67. Chandler et al does not specifically suggest a determination of which received signal provides accurate indication of the detected ear disorder. However since Chandler et al is in effect a proposal to extend conventional quantitation in scanning and Doppler mode to usage with their auditory canal array, it

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would have been generically obvious in view of Lang et al to use a signal selection process such as shortest distance, see col. 15 lines 22 – 35 in association with selection of transmission direction, see col. 17 lines 15-29 in order to characterize an interface distance or layer thickness.

Alternately stated, Lang et al evidences that the ultrasound-skilled diagnostician when faced with a problem such as quantitatively assessing swelling or tympanum displacement as in Chandler et al would apply generic techniques such as selecting a transducer or transducer direction from among different targeted directions for shortest-distance-to interface or in effect perpendicularity to interface in order that a displacement or layer thickness reading would have validity not obtainable on a slant. (Claims 1, 4, 16, 34-35, 38, 43, 46).

In the alternative, since Chandler et al as interpreted above calls also for Doppler mode measurement, it would have been obvious in view of Vilkomerson see abstract and Fig. 4 to provide a strongest signal selection from among different transducers or target directions for the measurement suggested in Lang et al in order to avoid artifact and assess flow with validity by genuinely overlying the vessel of interest. (Claims 1, 4, 16, 34-35, 38, 43, 46).

In either reference combination case all references teach the structure for and use of plural transducer arrays. (Claims 2-3, 32-33).

In the case of a single transducer, if claim 3 be so construed, Lang et al notes the equivalence of mechanical steering structure/steps using single transducers alternative to array use. (Claims 3, 33).

Array supports 2,4 and their use for supporting the contemplated curved array are additionally taught in Chandler et al. (Claims 5-6, 23-25, 39).

In the case of Lang et al, the 'certain ear portion' would be the nearest part of the interface of interest; in Vilkomerson it would be the diameter chord or midline centering through the underlying artery. (Claims 7, 18, 27, 42,48).

In either case the arrays must be operated sequentially for these assessments to obtain specificity of the different measurements for comparison. (Claim 8).

It is necessary in Chandler et al that the drive transducer and the receiving transducers be synchronized in order for the spatially specific pulse sampling to occur, see col. 10 lines 23-28. (Claims 9, 19).

The measurement method of Chandler et al necessarily involves imaging or measurement with the tympanum as a reflecting structure in the ultrasound wave path, see col. 6 lines 11-27 as well as additional middle ear echoes. (claims 10-11, 20-21,28-29).


The aforementioned direction-based selections for measurement in the secondary teachings are associated with specific transducers and therefore ultimately the method uses less than all transducers i.e. the single optimum transducer for the final diagnostic result. (Claim 12 and claim 14 as an interpretation distinct from the anticipatory one found supra, also claims 22, 30, 36-37, 40, 44-45).

The receipt of signals from other than a particular receiving transducer is part and parcel to the array steering in Chandler et al, see col. 5 lines 11-45. (Claims 13, 17, 26, 41,47).

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As noted above, Chandler et al contemplate a curved array see col. 7 top portion.
(Claim 15).

Any inquiry concerning this communication should be directed to Jaworski
Francis J. at telephone number 703-308-3061.



Francis J. Jaworski
Primary Examiner

FJJ:fjj

06-12-04